REMARKS

Applicants acknowledge receipt of the Office Action dated May 21, 2003, in which the Examiner objected to the specification and rejected claims 8 and 33 because of the use of trade names, and rejected claims 1-4, 6, 9-11, 13-16, 18-20, 22-25, 29, and 30-33 as anticipated by *Michelson* (U.S. Patent 6,537,320).

Applicant has amended the specification and claims to eliminate the use of trade names and has amended the claims to overcome the rejections over the art. For the reasons set out below, Applicants traverse these rejections.

§ 112 Rejections

In the specification and claims, the term "Phillips" has been replaced with "cross head" to describe a certain type of screwdriver.

In the specification and claims, the term "GFm" has been replaced with "the proteins described in U.S. Patent No. 5,290,763," which is the protein mixture that was sold under the trade name GFm at the time the application was filed.

Applicants submit that these rejections cure the grounds for the § 112 rejections.

§ 102 Rejections

In support of the rejection of claims 1-4, 6, 9-11, 13-16, 18-20, 22-25, 29, and 30-33 as anticipated by *Michelson*, the Examiner indicates the various features of the *Michelson* apparatus that appear to correlate to features in the presently claims apparatus. Applicants submit however, that this analysis fails to take into consideration the very different function and operation of the present device. Specifically, the present device is designed to allow a defect in the annulus of an intervertebral disc to be repaired, thus relieving the patient of the pain associated with a defective disc, while at the same time avoiding the distress and loss of function that results from spinal fusion.

See for example:

> "When the plug 30 is integrated with the annulus 15, the plug can provide a permanent seal of the defect 20." (p. 9, lines 19-20)
>
> "Once growth is completed, the defect 20 should be permanently sealed thereby, preventing further degeneration of the disc. The plug 30 may be used as a stand-alone treatment or in conjunction with treatments to retard disc degeneration such as discectomy." (p. 11, lines 20-23)

As disclosed throughout the specification, the present biodegradable member and matrix are inserted into the only. They do not contact either the adjacent vertebrae or their endplates, so as to avoid the growth of bone into or across the intervertebral space.

This is in direct contrast with the device disclosed by *Michelson*, which is "an interbody spinal fusion implant allowing for the growth of bone from vertebral body to vertebral body through the implant" (col. 3, lines 10-12). The implant of *Michelson* depends on removal of at least a portion of the defective disc so as to provide a mechanical interface that can be engaged by the implant. See:

> "Having described certain preferred embodiments of the implant of the present invention, the method for deploying this implant will now be described in more detail. The method comprises the steps of: *removing at least a portion of the disc from between the adjacent vertebral bodies so as to at least in part expose the vertebral endplates of those adjacent vertebral bodies.*" (col. 16, line 64 to col. 17, line3, emphasis added.)

Claims 1 and 19 have each been amended to recite that the biodegradable member is configured "such that upon insertion of the biodegradable member into the defect the defect is sealed and further such that use of the biodegradable member containing growth promoting matrix reduces or eliminates further degeneration of the annulus." This distinguishes the present apparatus and method from that of *Michelson*, whose teachings are directly opposed to the concepts underlying the present invention. Because *Michelson* teaches away from repairing a defective disc, let alone leaving it in place, the claimed invention is not obvious in view *Michelson*. For all of the foregoing reasons, claims 1 and 19, as well as the claims that depend from them, are allowable over the art of record.

New Claims

New dependent claims 34-37 have been added, which recite that use of the present implant avoids fusion of the vertebrae adjacent to the defective annulus, or that the present implant is configured conform to the size and shape of the defect. Both limitations are supported by the specification as filed. Neither limitation is taught or suggested by the art of record and the new claims are therefore also allowable.

Conclusion

For the reasons set out above, Applicants respectfully submit that the claims as amended are allowable over the art of record. Applicants therefore request that the Examiner reconsider and withdraw the rejections. If the Examiner has any questions or comments, or otherwise feels it would be advantageous, he is encouraged to telephone the undersigned at (713) 238-8043.

Respectfully submitted,

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